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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,999	03/30/2006	Claus Frohberg	65084.000018	9272

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HUNTON & WILLIAMS LLP
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EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
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1638

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06/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,999	Applicant(s) FROHBERG, CLAU S	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-22 and 24-25 are currently pending. Claims 1-22 and 24-25 are examined on the merits herein.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The Specification contains 12 hyperlinks, 4 in paragraph 41, 1 each in paragraphs 15, 42, 43, 45, 79 and 229, and 2 in paragraph 78. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: There is no Brief Description of Figures in the specification for Tables 1-3 of the drawings. Furthermore there appears to be a different Table 1 contained in the specification that does not correspond to Tables 1 in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If

the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a genetically modified plant cell comprising SEQ ID NO:3 or nucleic acid encoding SEQ ID NO:4, does not reasonably provide enablement for any modified plant cell with an increase in activity of any Class 3 branching enzyme, wherein the modification is a nucleic acid sequence with as little as 50% identity to SEQ ID NO:3, or a nucleic acid that encodes an amino acid with as little as 50% identity to SEQ ID NO:4, or any nucleic acid that hybridizes to SEQ ID NO:3 under unspecified stringent conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a genetically modified cell of any plant species, modified with any nucleic acid wherein any class 3 branching enzyme has increased activity in comparison with wild type plant cells, and genetically modified plant cells with

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any foreign nucleic acid that encodes an amino acid having as little as 50% identity with SEQ ID NO:4, or any foreign nucleic acid that merely hybridizes under unspecified conditions to SEQ ID NO:3 or a nucleic acid that encodes SEQ ID NO:4, plants and methods of manufacturing transgenic plants comprising the multitudes of nucleic acid molecules broadly claimed.

In contrast, the specification only provides guidance for modifying a potato plant cell with a construct comprising a single PCR fragment of SEQ ID NO:3, wherein the transcript encoding a class 3 branching enzyme is increased. The specification does not give guidance to any other constructs, or any other modifications of SEQ ID NO:3, or any other gene that lead to the claimed increase in a class 3 branching enzyme activity.

Class 3 Branching Enzyme

Applicants have defined a class of enzymes based on their identity to the potato-specific branching enzyme disclosed in SEQ ID NO:4. However, the specification does not detail any domains or any activity that is specific to SEQ ID NO:4 that would enable one of skill in the art to recognize embodiments that are encompassed by the instant claims. In fact, the domains disclosed in the specification are common to all starch branching enzymes. Applicants have detailed several examples of enzymes purported to belong to both Class I and Class II branching enzymes, but disclose only SEQ ID NO:4 as Class III and no other examples that would provide guidance for classification other than a "higher degree of identity with the amino acid sequence shown in SEQ ID NO:4 than that with that of the branching enzyme BE I from maize (GenBank Acc:

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D11081) or with that of the branching enzyme BE IIb from maize (GenBank Acc: AF072725)". The specification does not acknowledge how to classify enzymes that belong to this category that have already been classified by Applicants as belonging to Class I or II. Nor does the specification acknowledge which particular features of the recited sequence are responsible for its classification. Without more specific guidance as to what constitutes a class 3 branching enzyme, Applicants are not enabled for modified plant cells that increase the activity of any class 3 branching enzyme, particularly where no other class 3 branching enzymes are known.

Hybridization

The claims include embodiments of nucleic acids that hybridize under "stringent" conditions to SEQ ID NO:3. The specification discloses stringent conditions as "such as, for example, are described in Sambrock et al..." on page 42. Not only does the specification not limit guidance of stringent conditions to Sambrock et al which is but one example of said conditions, but Sambrock et al recite a variety of hybridization conditions, dependent upon application of which are considered stringent or non-stringent. The specification does not disclose so much as a single embodiment that is defined by its hybridization to SEQ ID NO:3, and the specification, lacking guidance for specific hybridization conditions, does not enable one of skill in the art to practice the invention commensurate in scope with the claims as it relates to hybridization conditions.

Unpredictable Starch Phenotypes

The synthesis of starch in plants is complex and unpredictable. In a review of the regulation of starch metabolism in plants Tetlow et al (2004 Journal of Experimental Botany 55(406):2131-2145) discuss the developments that help understand the regulation of starch metabolism in higher plants. Tetlow et al disclose that the function of any particular starch depends on the type of plastid it is synthesized in and the type of plant tissue it is derived from (see page 2131 Column 2, lines 3-5). Tetlow et al also disclose that only a few genetic variations that lead to known phenotypes are even known for starch branching enzymes as evidenced by the statement "To date, only mutations in SBEII isoforms give clear phenotypes, and in monocots this is confined to SBEIIb mutants" (see page 2134 second column, last paragraph). Furthermore the affect these variations have on starch derived from the endosperm is unpredictable. Tetlow et al disclose a mutant of SBEIIa that displayed a clear phenotype in leaf starch but showed no alterations in the storage starch of the endosperm (See page 2134 Column 2, last paragraph, for example). Tetlow et al further disclose that other genes are capable of affecting the expression of at least SBEIIb, but not all of these genes are known (see page 2135, 1st column, 3rd paragraph, for example). Without a clear guidance as to the specific genetic variation, it would be undue experimentation to evaluate all genetic variations of all genes affecting the level of already established starch branching enzyme classes, let alone the newly defined class 3 branching enzymes that are even less characterized as broadly claimed.

Given the state of the art, the disclosure by Tetlow et al, lack of a working examples, and absence of guidance as discussed above and the unpredictability as

discussed above, it would be undue experimentation for one of skill in the art to isolate and evaluate all exogenous nucleic acids that would lead to an increase of any class 3 branching enzyme as broadly claimed.

Claims 1-22 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a genetically modified cell of any plant species, modified with any nucleic acid wherein any class 3 branching enzyme has an increased activity in comparison with wild type plant cells, and genetically modified plant cells with any foreign nucleic acid that encodes an amino acid having as little as 50% identity with SEQ ID NO:4, or any foreign nucleic acid that merely hybridizes under unspecified conditions to SEQ ID NO:3 or a nucleic acid that encodes SEQ ID NO:4, plants and methods of manufacturing transgenic plants comprising the multitudes of nucleic acid molecules broadly claimed.

In contrast, the specification only describes a single construct comprising a PCR fragment of SEQ ID NO:3, wherein the activity of a class 3 branching enzyme is increased. The specification does not describe any other constructs, or any other modifications of SEQ ID NO:3, or any other gene that when provided exogenously leads to the claimed function, namely an increased activity of a class 3 branching enzyme.

Class 3 Branching Enzyme

Applicants have defined a class of enzymes based on their identity to the potato-specific branching enzyme disclosed in SEQ ID NO:4. However, the specification does not describe any domains that are specific to SEQ ID NO:4 but not to the other classes of branching enzymes. Without a description of the defining characteristics of embodiments, one would not be able to determine whether or not Applicants are in possession of the claimed embodiments that are encompassed by the instant claims. In fact, the domains disclosed in the specification are common to all starch branching enzymes. Applicants have detailed several examples of enzymes purported to belong to both Class I and Class II branching enzymes, but describe only one example (SEQ ID NO:4) as Class III and no other examples that would provide guidance for classification other than a "higher degree of identity with the amino acid sequence shown in SEQ ID NO:4 than that with that of the branching enzyme BE I from maize (GenBank Acc: D11081) or with that of the branching enzyme BE IIb from maize (GenBank Acc: AF072725)".

Hybridization

The claims include embodiments of nucleic acids that hybridize under "stringent" conditions to SEQ ID NO:3. The specification describes stringent conditions as "such as, for example, are described in Sambrock et al..." on page 42. Not only does the specification not limit the description of stringent conditions to Sambrock et al which is but one example of said conditions, but Sambrock et al recite a variety of hybridization conditions, dependent upon application of which are considered stringent or non-stringent. The specification does not describe even so much as a single embodiment

that is defined by its hybridization to SEQ ID NO:3, and the specification, lacking a description for specific hybridization conditions, lacks written description for embodiments that hybridize to SEQ ID NO:3.

Description of which amino acids may be substituted

Applicants also do not describe which of the amino acids of SEQ ID NO:4 are absolutely required for the function of class 3 branching activity. Without a description of which amino acids are required, there is also a lack of description as to which amino acids would need to be modified to reduce the activity of the class 3 branching enzyme. The claims embody sequences that have as little as 50% identity to SEQ ID NO:4 which encompass a multitude of embodiments that have anywhere from 1 amino acid to 452 amino acids that are either substituted, deleted, or inserted in any combination along any length of the sequence. The literally billions of embodiments are not described sufficiently for one to determine that Applicants were in possession of a representative number of embodiments. Furthermore, there is no description of which amino acids may be substituted and which are critical to the function of the class 3 branching enzyme.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the

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absence of knowledge as to what that material consists of, is not a description of that material.” Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the genus of sequences required for making the claimed wheat grain, any method of using them, such as

transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 rejected under 35 U.S.C. 102(b) as being anticipated by EP 1103617A2 (published 5/30/2001).

The claims are broadly drawn to a modified plant cell, a plant comprising said plant cell, propagation materials and harvestable plant parts of said plant, a method for the manufacture of said genetically modified plant, wherein the plant cell is modified by introducing a foreign nucleic acid molecule that codes a Class 3 branching enzyme, wherein the nucleic acid molecule may have as little as 50% identity with a nucleic acid that encodes SEQ ID NO:4, or 50% identity with SEQ ID NO:3, merely hybridize under unspecified conditions to SEQ ID NO:3 or a nucleic acid that encodes SEQ ID NO:4, or any fragments or derivatives of these nucleic acid molecules, wherein the plant is a potato plant.

The published European Patent Application, EP1103617A2 teaches potato plant cells transformed with genetic constructs comprising a branching enzyme that modifies the starch content of the harvested potato tubers (see claims, Example 2 in particular, and page 7 of the Application). The transformation methods, including regeneration of the plant are disclosed on page 7. The sequence by its nature of being a branching enzyme is considered to meet the limitations of a Class 3 branching enzyme given that the specification does not disclose any features that differentiate a Class 3 branching enzyme from other branching enzymes. Furthermore, the function as demonstrated by the Application is the only requirement, as the limitations for the foreign nucleic acid molecules of the instant application only require fragments or derivatives of SEQ ID NO:3, which may include as little as 2 bp of the sequence, which is an inherent feature of the cited art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1103617A2 as applied to claims 1-17 above, and further in view of Cooke et al (US patent 6825342, filed 5/03/1996).

The claims are broadly drawn to a modified plant cell, a plant comprising said plant cell, propagation materials and harvestable plant parts of said plant, a method for

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the manufacture of said genetically modified plant, wherein the plant cell is modified by introducing a foreign nucleic acid molecule that codes a Class 3 branching enzyme, wherein the nucleic acid molecule may have as little as 50% identity with a nucleic acid that encodes SEQ ID NO:4, or 50% identity with SEQ ID NO:3, merely hybridize under unspecified conditions to SEQ ID NO:3 or a nucleic acid that encodes SEQ ID NO:4, or any fragments or derivatives of these nucleic acid molecules, wherein the plant is a potato plant, and methods of obtaining a modified starch therefrom.

The published European Patent Application, EP1103617A2 teaches potato plant cells transformed with genetic constructs comprising a branching enzyme that modifies the starch content of the harvested potato tubers (see claims, Example 2 in particular, and page 7 of the Application). The transformation methods, including regeneration of the plant are disclosed on page 7. The sequence by its nature of being a branching enzyme is considered to meet the limitations of a Class 3 branching enzyme given that the specification does not disclose any features that differentiate a Class 3 branching enzyme from other branching enzymes. Furthermore, the function as demonstrated by the Application is the only requirement, as the limitations for the foreign nucleic acid molecules of the instant application only require fragments or derivatives of SEQ ID NO:3, which may include as little as 2 bp of the sequence, which is an inherent feature of the cited art.

EP1103617A2 does not teach methods of isolating modified starch.

Cooke et al (US Patent 6825342, filed 5/03/1996) teach methods of isolating modified starches from potato plants transformed with genetic constructs altering the activity of branching enzymes in potato (see claims, for example).

It would have been obvious to one of ordinary skill in the art to isolate the starch from the potato tubers taught by EP 1103617A2 using the methods taught by Cooke et al. EP 1103617A2 mentions the measurement of amylose and amylopectin ratios and teaches a modified starch. One of ordinary skill in the art would have readily appreciated the teachings of Cooke et al, and indeed, the state of the art at the time of invention, readily would have equipped one of ordinary skill in the art to isolate said starch. Given the state of the art and the disclosures by Cooke et al and European Patent Application 1103617A2, it would have been obvious to transform a potato plant with a class 3 branching enzyme as taught by EP 1103617A2 and isolate the modified starch as taught by Cooke et al.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/

Primary Examiner, Art Unit 1638

June 5, 2008